

Criminal Indictment for Human Error

Serious medication errors occur in healthcare as a result of both human and system factors. When a practitioner makes a mistake due to human error that results in a patient death, should that clinician be criminally indicted? Unfortunately, this can happen in many states, due to criminal laws and federal or state regulations.

This occurred to one nurse who was criminally indicted after accidentally administering intravenous (IV) vecuronium instead of Versed (midazolam) which resulted in the patient's death. The patient was ordered 1 mg IV Versed for anxiety to be administered prior to a radiology exam. The nurse entered the first two letters of the brand drug name "VE" into the search field of the automated dispensing cabinet (ADC). "Versed" did not appear as the ADC defaulted to generic drug name searches. The nurse was not aware that the setting could be changed to search by brand name. She then over-rode the ADC safeguards, entered "VE" into the search field, and selected the medication at the top of the list, which was vecuronium, not Versed. While vecuronium is on the hospital list of high-alert medications, there was no warning of potential respiratory arrest given prior to removing the drug from the ADC. The nurse did not notice or misunderstood a warning on the vial that stated: "Warning: Paralyzing Agent". She administered the drug and left the patient to attend to her other duties in another department. The patient became unresponsive, suffered anoxic brain injury and died. This fatal mistake led to felony charges of reckless homicide and abuse of an impaired adult. The nurse could face two to 12 years in prison and a large fine. Her nursing license can also be restricted or revoked.

Many believe this mistake can occur in any hospital due to underlying system issues such as:

- ADCs that pre-populate a drug name after entering only two letters
- ADCs that do not search both brand and generic names concurrently
- ADCs that do not display an interactive warning on the screen that mandates the selection or verification of a neuromuscular blocker's use followed by an alert for the need to ventilate the patient
- No supplemental warnings on neuromuscular blocker vials and/or storage areas
- Ineffective manufacturers' warnings on neuromuscular blocker vials (Warning: Paralyzing Agent), which have either been missed or misunderstood by clinicians
- Confusion regarding the policies on limited use of overrides
- Lack of protocols that outline the monitoring requirements for patients who are given IV midazolam for anxiety rather than for moderate sedation

Humans make mistakes. During a time when clinicians are expected to carry heavy patient loads and assume more responsibilities with fewer resources and limited time, some may feel pressured to take short-cuts to get their work done which can lead to missteps. When fatal errors occur, the healthcare provider becomes a second victim. In other words, clinicians who are involved in serious adverse events may also suffer post-traumatic stress disorder (PTSD) from the event, including feelings of depression, shame, and guilt. Fatal errors may haunt second victims for their entire lives.

^{1.} Institute for Safe Medication Practices. (2018). *Nurse Advise-ERR*. Retrieved from Institute for Safe Medication Practices: http://www.ismp.org/newsletters/nursing/issues/NurseAdviseERR201902.pdf

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Are criminal charges justified in the case of human error even when there is no intent to cause harm? Unfortunately, "intent to harm" is no longer needed for an action to be considered a crime. Human error that arbitrarily occurs is now considered "criminal" in situations where public safety is an issue.

The ADC override option is available in every hospital that utilizes ADCs and is a function that is often used to obtain emergency drugs quickly to avoid a delay in treatment that could negatively affect patient care. However, the override feature may also be needed for medications and solutions in hospitals that do not have 24-hour pharmacy services. Employing the override function is considered by many a common practice and "acceptable risk" to provide care to patients.

The underlying issue in this case was not the nurse's judgment in using the override function to obtain the medication; instead, there are no systems in place to prevent or detect the wrong drug. Safety experts and many licensing boards agree that criminal charges should only be pressed in rare cases when there is intentional harm caused without reasonable benefit.

Criminal prosecution will not necessarily improve patient safety; rather, it can have a negative impact and may:

- Discourage clinicians to report errors
- Support a culture of blame
- Prevent the transition to a culture of safety
- Compel practitioners to leave clinical practice
- Aggravate the shortage of clinicians
- Sustain the myth that performance can be perfect
- Impede system improvements
- Decrease staff morale
- Inhibit nurses from appropriately carrying out their jobs (i.e. not retrieving emergency drugs from an ADC via override, delaying treatment, and resulting in patient harm)

Healthcare leaders should be accountable for safety system design. However, many biases exist perpetuating the culture of blame.

- Some assume that catastrophic medication errors will not happen in their facility.
- If errors occur, these leaders may not be equipped to deal with it, may underestimate the effects and resort to punishments that are ineffective and unfair.
- Others may miss underlying system failures that contribute to an error and instead focus only on the frontline nurse's failure to follow the "five rights"

Leaders should:

- Recognize that errors are going to happen
- Proactively improve system designs based on lessons learned by other leaders and organizations
- Share accountability
- Design changes to improve safety within their organization

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- Avoid severity bias an opinion in which errors that lead to more harm are more blameworthy and punishable than the same error that does not lead to harm
- Establish a Just Culture
 - Do not define accountability based on the error or severity of its outcome, rather by the quality of one's actions
 - Do not ask whether harm occurred, but whether the individual consciously engaged in reckless behavior
 - Coach clinicians who perform at-risk actions to recognize the risk associated with the behavior
 - Change system issues that cause at-risk behaviors

Strategies to reduce the risk of a similar fatal error:

- Establish a standard policy for patients who need anxiety relief for claustrophobia before radiology procedures that utilizes an oral anxiolytic (i.e. lorazepam) and includes patient monitoring requirements.
- Do not store neuromuscular blockers in areas where they are not routinely needed or used.
 - In units outside the perioperative area (i.e. critical care, emergency department), store the neuromuscular blockers in a sealed box or rapid sequence intubation (RSI) kit.
 - If storing the drugs in ADCs, keep them in locked-lidded pockets.
- Place warnings on all storage locations and/or ADC pockets/drawers/lids that contain neuromuscular blockers (i.e. WARNING: CAUSES RESPIRATORY ARREST – PATIENT MUST BE VENTILATED). The warning labels should be visible when emergency kids and ADC pockets/drawers/lids are open.
- Place warning labels directly on all neuromuscular blocker vials and other containers.
- Create an interactive warning (i.e. **Patient must be intubated to receive this medication**) on ADC screens that requires the user to enter the purpose of the medication and/or verify that the patient is or will be manually or mechanically ventilated.
- Review the hospital's ADC override policy and verify that it should only be used in emergency situations when a patient could be significantly harmed by delays caused by pharmacy review (i.e. antidotes, rescue/reversal agents, lifesaving medications, drugs for acute pain and uncontrolled vomiting).
- Limit overrides to a few medications and avoid overrides for high-alert medications. Each override should depend on the situation and should be justified, and not based only on its availability on a list of overridable medications.
- Require an independent double check by another clinician to verify the medication and indication. Include an automated prompt (i.e. "Witness on removal") and mandate documentation of a witness at the ADC when removing medications via override.
- Implement barcode medication administration (BCMA) scanning verification in all areas.

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- Require patient monitoring for patients who receive sedation regardless of the indication or setting. Policies and procedures should outline the required monitoring, such as pulse oximetry, and criteria for when it can be stopped.
- Educate nurses to use profile mode (whenever possible) when removing medications from an ADC. Profile mode only releases patient-specific medications that have been verified by a pharmacist.
 - Ensure nurses understand the safety risks when obtaining medications via override as well as the required safeguards for drugs removed via override such as mandatory patient monitoring parameters.
- Assess overrides daily to verify appropriateness, transcription of orders, and documentation of administration. Follow up on any overrides that are not appropriate or do not have an order. Review aggregate override usage reports monthly to assess appropriateness and to address how pharmacists review medication orders prior to removal.

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